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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/518,098 03/03/00 SHAPIRO L 114232.107

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PEPPER HAMILTON
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WASHINGTON DC 20005

EXAMINER

LUKTON, D
ART UNIT PAPER NUMBER

1653 //

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/518,098	Applicant(s) Shapiro
	Examiner David Lukton	Art Unit 1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jun 25, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.

4a) Of the above, claim(s) 1-39 and 43-45 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 40-42 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
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| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 20) <input type="checkbox"/> Other: _____ |

Applicant's election of Group 13 with traverse is acknowledged.

Applicants have traversed the restriction by arguing that the restriction between groups 13 and 14 is improper, since the two groups are identical, and two patents should not be issued for the same invention. The examiner would agree that, in the event that all embodiments of claim 40 prove to be novel, it would not be appropriate to maintain the restriction between Groups 13 and 14. The intention of the examiner, in fact, is to rejoin Groups 13 and 14 if that proves to be the case. However, it may well prove to be the case that a valid §102 or §103 rejection can be found which is applicable to either Group 13 or Group 14. Should that happen, applicants may choose to amend the claims in such a way as to "unmask" the distinction between Groups 13 and 14. Applicants have also argued that the examiner should also examine claim 36 (and claims dependent thereon). However, the "invention" of claim 36 is quite different from that of Groups 13-14. Claim 36 is drawn to any peptide or other compound which applicants believe exhibits the same activity as *alpha*-1-antitrypsin. First, *alpha*-1-antitrypsin *per se* is known in the prior art. But even if this were not the case, the fact is that compounds which exhibit "AAT-like" activity encompass serine protease inhibitors generally. There is a vast multitude of disclosures on serine protease inhibitors, even if it is also true that very few of them disclose that such inhibitors are effective against HIV. Applicants have also argued that claim 36 should be rejoined because the examiner stated that if a group containing claim 36 were elected and found

allowable, the corresponding method-of-use claims would be rejoined. While it may be true that such method-of-use claims would have been rejoined, the converse is by no means true. That is, if an applicant elects claims drawn to a method of using composition "X", the examiner bears no obligation to examine claims drawn to composition "X" *per se*. Applicants have also argued that claims 10-11 should be joined with the elected group. In the event that claims 40-42 prove to be novel in all embodiments, it would be appropriate to revisit the matter of restriction between Group 13 (on the one hand), and claims 10-11 (on the other hand). However, it may turn out to be the case that serine protease inhibitors have been asserted (in the prior art) to be inhibitors of HIV replication. If such references can be produced by the examiner, the finding of such would argue against rejoining claims 10-11 with the elected group, even if claims 40-42 prove to be novel. As for the matter of joining two or more of the non-elected groups (other than claims 10-11), the point is moot. If the examiner were to state that all such non-elected groups were joined together with one another, the resulting group would still be non-elected. The restriction is maintained at the present time. Claims 1-39 and 43-45 are withdrawn from consideration.

*

Applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The first specie is a specific compound (encompassed by Group 13) which exhibits AAT activity or AAT-like activity. The second specie is either a specific HIV

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protease inhibitor, or a specific HIV reverse transcriptase inhibitor.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1600